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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/632,810	08/04/2003	Atsushi Suzuki	241113US0DIV	4609

22850 7590 09/26/2006

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EXAMINER	
UNDERDAHL, THANE E	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,810	SUZUKI ET AL.	
	Examiner	Art Unit	
	Thane Underdahl	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8 and 11-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8 and 11-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08/04/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/24/2005 and 6/28/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.
Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-6, 8, and 11-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,310,100 in view of Abraham (Food and chemical toxicology, 1996) as supported by Hsu (U.S. Patent # 5,958,417) and Yokozawa et al. (Phytotherapy Research, 1995). Although the conflicting claims are not identical, they are not patentably distinct from each other because both inventions disclose treatments for hypertension comprised of ferulic acid or a derivative thereof. The therapeutic compositions comprising ferulic acid and its derivatives may further comprise pharmaceutical products, nutritional supplements or products, and foods. The reference does not specifically claim chlorogenic or caffeic acid in combination with ferulic acid,

but in claim 5 it does disclose a composition "consisting essentially of ferulic acid or a derivative thereof, and at least one other anti-hypertensive compound," which would encompass chlorogenic and caffeic acid as supported by Hsu (col 2, lines 58-60) and Yokozawa et al. (page 107, Table 1). Abraham discloses such compositions of isolated ferulic, chlorogenic, and caffeic acid that can be used to supplement food (Table 1, Code C and C+D). One of ordinary skill in the art would be motivated by U.S. Patent # 6,310,100 to combine chlorogenic and caffeic acids, which are known anti-hypertensive agents to a composition comprising ferulic acid with the expectation of successful treatment for hypertension with such a composition as supported by Hsu and Yokozawa et al.

2. Claims 1-6, 8, and 11-19 are provisionally rejected on the ground of nonstatutory double patenting over claims 1-26 of copending Application No. 11/209,672, claims 2-6, 8,11-16 and 20-29 of copending Application No. 10/826,289 and claims 1-19 of copending Application No. 09/922,694. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application are fully disclosed in the referenced copending applications and would be covered by any patent granted on either of those copending applications since the referenced copending applications and the instant application are claiming common subject matter, as follows: A treatment of hypertension using compositions of ferulic, chlorogenic, and caffeic acid.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

copending applications. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims depend from claim 11 which discloses a treatment for hypertension or high blood pressure (McGraw-Hill, definition of "hypertension"). The broadest reasonable interpretation of hypertension and high blood pressure included an increase in both the diastolic and systolic blood pressures. Dependant claim 12 is drawn to a decrease in systolic blood pressure while dependant claim 13 is drawn to a decrease in diastolic blood pressure. It is unclear if the applicant is treating only one component of hypertension independently or both symptoms simultaneously. Clarification is required

5. Claims 3, 4, 5 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims include "a chlorogenic acid" and list a group that "the chlorogenic acid is selected from the group consisting of : neochlorogenic acid, an isochlorogenic acid, 3,5-dicaffeoylquinic acid, cryptochlorogenic acid and 5-caffeoylquinic acid." However chlorogenic acid is a well defined individual compound registered by CAS (327-97-9). It is unclear what compound is being

selected in claim 4 in the composition of claim 1. The identity of the compound in claims 5 or 19 is also unclear, whether it is chlorogenic acid or "a chlorogenic acid". Clarification is required.

6. Claims 3, 4, and 5 recites the limitation "a chlorogenic acid" in the composition of claim 1. There is insufficient antecedent basis for this limitation in the claim. Claim 1 is drawn to chlorogenic acid which has a defined structure and CAS registry number. The phrase "a chlorogenic acid" is unclear and may refer to a derivative that is not mentioned in claim 1. Clarification is required.

7. Claims 14, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrases "rise in...blood pressure" or "rise of...blood pressure" are queried. It is unclear to the Examiner what is being prevented since normal blood pressure fluctuates between 140/90 mmHg and normal cardiovascular operation depends on the continuous rise and fall of the diastolic and systolic pressures.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Abraham et al. with support from Clarke et al. (Coffee Volume 3: Physiology, 1988) and Macheix et al. (Fruit Phenolics, 1990).

9. These claims are drawn to a composition comprising at least two parts a) ferulic acid in combination with b) caffeic acid, or chlorogenic acid or a combination of the two.

The composition can be a beverage or supplement. Other acids that can be included in the composition are neochlorogenic acid, an isochlorogenic acid, 3,5-dicaffeoylquinic acid, cryptochlorogenic acid and 5-caffeoylquinic acid.

10. Abraham teaches a composition that contains ferulic acid in combination with caffeic acid and chlorogenic acid. (page 16, Table 1, Code C). This composition was included as a supplement to the beverage coffee (page 16, Table 1, Code C+D). Coffee contains isochlorogenic acid as well as neochlorogenic acid and 5-caffeoylquinic acid as supported by Clarke et al. (page 41 2nd paragraph) and Macheix et al. (page 23, 3rd paragraph).

11. The applicant did use the narrow claim language of "consisting" in claims 2, 3, and 4. However these claims depend from a broader independent claim 1, that uses the open language of "comprising" so while they may limit that portion of the independent claim, they do not limit the entire independent claim which may contain other components.

12. Therefore the applicant's invention is anticipated by reference of Abraham et al.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abraham as applied above in view of Hsu (U.S. Patent # 5,958,417) as supported by McGraw-Hill ("hypertension." McGraw-Hill Encyclopedia of Science and Technology) and Yokozawa et al. (Phytotherapy Research, 1995).

14. These claims are drawn to a method of treatment for hypertension or high blood pressure and also for reducing a rise in blood pressure using compositions of ferulic acid.

15. Abraham in the rejection listed above, anticipated the compositions of claim 1 and 8 by teaching a composition containing ferulic acid with chlorogenic acid and caffeic acid (page 16, Table 1, Code C). This composition can be a supplement added to coffee (page 16, Table 1, Code C+D).

16. What Abraham does not teach is the use of his composition in hypertension. The broadest definition of hypertension includes both high systolic and high diastolic pressure as supported by (McGraw-Hill, definition of "hypertension"). Therefore one of ordinary skill in the art would recognize that the treatment of hypertension by this definition includes treating both the high systolic and high diastolic pressures.

17. While Abraham does not teach his compositions for use as a treatment of hypertension, Hsu does. Hsu teach that *Crataegus* is a common herb used to treat hypertension and it contains the active ingredients of chlorogenic acid and caffeic acid (Hsu, col 2, lines 58-61). Yokozawa et al. supports Hsu by teaching that caffeic acid and its derivatives are effective at treating hypertension (page 107, Table 1).

It would have been obvious to someone skilled in the art, knowing the teachings of Hsu, to treat hypertension using the composition of Abraham. Hsu provides the motivation by plainly stating that caffeic acid and chlorogenic acid are known treatments for hypertension. The reasonable expectation of success is provided by Hsu who states that *Crataegus* with its active ingredients of chlorogenic acid and caffeic acid are used to treat hypertension.

Therefore the applicant's invention was obvious over the references of Abraham et al. in view of Hsu et al.

In summary no claims, as written, are allowed for this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thane Underdahl whose telephone number is (571) 272-9042. The examiner can normally be reached on 8:00 to 17:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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